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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,244

09/29/2005

Dipti Sareen

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8727

28213 7590 12/31/2008  
DLA PIPER LLP (US)  
4365 EXECUTIVE DRIVE  
SUITE 1100  
SAN DIEGO, CA 92121-2133

EXAMINER

ZARA, JANE J

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

12/31/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,244	<b>Applicant(s)</b> SAREEN ET AL.	
	<b>Examiner</b> Jane Zara	<b>Art Unit</b> 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-9 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This Office action is in response to the communication filed 10-3-08.

Claims 1-9 are pending in the instant application.

### ***Election/Restrictions***

This application contains claims 4 and 5, drawn to an invention nonelected without traverse in the reply filed on 11-15-07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Response to Arguments and Amendments***

#### **Withdrawn Rejections**

Any rejections not repeated in this Office action are hereby withdrawn.

#### **Maintained Rejections**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bornemann et al (Biochem. J., Vol. 325, pages 623-629, 1997) for the reasons of record set forth in the Office action mailed 7-3-08 and as set forth below.

Applicant's arguments filed 10-3-08 have been fully considered but they are not persuasive. Applicant argues that the teachings of Bornemann are mere elucidations of the biosynthesis of mycothiol and that Bornemann is absolutely silent with regard to inhibitors of cysteine:glucosaminy l inositol ligase and methods of identifying such inhibitors.

Contrary to Applicant's assertions, Bornemann discloses both the means and motivation to screen for potential inhibitors of cysteine:glucosaminy l inositol ligase. See, for example page 625 which describes in the "Enzyme assays" section the means for detecting cysteine ligase activity, using  $\alpha$ -D-Gl, ATP, magnesium acetate and L-[<sup>35</sup>S]cysteine under various conditions, *e.g.*, in the presence and absence of acetyl-S-CoA. Applicant is correct that Bornemann elucidates the various steps involved in the biosynthesis of mycothiol, but, contrary to Applicant's assertions, the elucidation of mycothiol biosynthesis includes the development of various assay systems that can be relied upon to screen for inhibitors of the various enzymatic steps involved in mycothiol biosynthesis, including the instantly claimed cysteine-glycosaminy l inositol ligase. Bornemann for instance teaches the rates of catalysis of cysteine ligase in the presence of various substrate isomers, providing guidance and insight about the instantly claimed enzyme's substrate preferences (see page 628, section entitled "Specificity of  $\alpha$ -D-Gl-cysteine ligase": "This finding indicates a pronounced selectivity for the natural

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substrate, particularly with regard to the configuration of the inositol moiety, as compared with the  $\alpha$ -L-isomer.”

Bornemann unambiguously states in the introduction of the paper (p. 624) that “the production and utilization of mycothiol are pathogen-specific processes that can potentially be exploited as **drug targets**.” (emphasis added) And since the development of an assay for the instantly claimed cysteine:glucosaminyl inositol ligase is a central focus of Bornemann paper, this particular enzyme is also to be exploited as a “drug target.”

What’s more, the final paragraph of Bornemann clearly teaches the use of the newly disclosed assays for cysteine:glucosaminyl inositol ligase in drug discovery research, e.g., to test for potential inhibitors of cysteine:glucosaminyl inositol ligase, as instantly claimed:

The present study paves the way for the characterization of the newly discovered enzyme activities and **for the design of potential inhibitors** of the biosynthesis of mycothiol, which in turn could be of value in studies of its function. Strategies for the design of ligase inhibitors were evolved by Meister and his colleagues and were further elaborated in studies of...., an enzyme involved in peptidoglycan biosynthesis.

(citations omitted, emphasis added).

For these reasons, the instant rejection is maintained.

***Allowable Subject Matter***

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**Jane Zara**  
**12-29-08**

/Jane Zara/  
Primary Examiner, Art Unit 1635